



Billing Code 4410-09-P

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**[Docket No. DEA-353E]**

**Established Assessment of Annual Needs for the List I Chemicals Ephedrine,  
Pseudoephedrine, and Phenylpropanolamine for 2012**

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice.

**ACTION:** Notice.

**SUMMARY:** This notice establishes the initial 2012 assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

**EFFECTIVE DATE:** [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]

**FOR FURTHER INFORMATION CONTACT:** John W. Partridge, Chief, Liaison and Policy Section, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 307-7184.

**SUPPLEMENTARY INFORMATION:**

**Background**

The 2012 assessment of annual needs represents those quantities of ephedrine, pseudoephedrine, and phenylpropanolamine which may be manufactured domestically and imported into the United States in 2012 to provide adequate supplies of each chemical to meet the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks of such chemicals. Section 306 of the Controlled Substances Act (CSA)

(21 U.S.C. 826) requires that the Attorney General establish an assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100.

On September 14, 2011, a notice entitled “Proposed Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2012” was published in the Federal Register (76 FR 56809). That notice proposed the 2012 assessment of annual needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), phenylpropanolamine (for sale), and phenylpropanolamine (for conversion). All interested persons were invited to comment on or object to the assessments on or before October 14, 2011.

### **Comments Received**

DEA received one comment regarding the proposed assessment of annual needs for pseudoephedrine. The commenter stated that “the quotas should be increased to cover our needs. The appropriate DEA Form 250 will be submitted shortly pertaining to the items for which we submitted comments.” As of October 17, 2011, the commenter was not registered to manufacture the chemical pseudoephedrine and DEA had not received the commenter’s request for 2012 quota for pseudoephedrine. DEA will consider the commenter’s request for quota after they become registered to manufacture pseudoephedrine and submit a quota application pursuant to 21 CFR 1315.22.

### **Conclusion**

In determining the 2012 assessments, DEA took into account the criteria that DEA is required to consider in accordance with 21 U.S.C. 826(a) and 21 CFR 1315.11. DEA has increased the assessment of annual need for ephedrine (for sale) and pseudoephedrine

(for sale) over the proposed amount based on additional data that was received regarding the total net disposals (i.e. sales) of these List I chemicals for the current and preceding two years, actual and estimated inventories, projected demand (2012), industrial use, and export requirements. The relevant inventory, acquisition (purchases), and disposition (sales) data was provided by DEA registered manufacturers and importers in procurement quota applications (DEA 250), manufacturing quota applications (DEA 189), import quota applications (DEA 488), and declarations for import and export received by DEA as of October 17, 2011. After reviewing the additional data, DEA determined that an increase in the proposed assessment of annual need for ephedrine (for sale) and pseudoephedrine (for sale) was warranted. This notice reflects that increase.

In accordance with 21 U.S.C. 826 and 21 CFR 1315.11, the Administrator hereby determines that the 2012 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in kilograms of anhydrous acid or base, is established as follows:

<b>List I Chemical</b>	<b>Established 2012 Assessment of Annual Needs</b>
Ephedrine (for sale)	4,000 kg
Phenylpropanolamine (for sale)	5,200 kg
Pseudoephedrine (for sale)	258,000 kg
Phenylpropanolamine (for conversion)	26,200 kg
Ephedrine (for conversion)	12,000 kg

The assessment of annual needs may be adjusted at a later date pursuant to 21 CFR 1315.13.

\_\_\_\_\_  
Dated:  
December 1, 2011

\_\_\_\_\_  
Michele M. Leonhart  
Administrator

[FR Doc. 2011-31777 Filed 12/09/2011 at 8:45 am; Publication Date: 12/12/2011]